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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/768,744

02/02/2004

Christopher Hunter

120-000220US

4909

22798

7590

06/16/2010

QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.

P O BOX 458

ALAMEDA, CA 94501

EXAMINER

WOODWARD, CHERIE MICHELLE

ART UNIT

PAPER NUMBER

1647

MAIL DATE

DELIVERY MODE

06/16/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/768,744	Applicant(s) HUNTER ET AL.	
	Examiner CHERIE M. WOODWARD	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 11, 12, 20, 21, 24-26, 74 and 75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 11, 12, 20, 21, 24-26, 74, and 75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/18/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/18/2010 has been entered.

Formal Matters

2. Claims 2-6, 7-10, 13-19, 22-23, and 27-73 have been cancelled by Applicant. New claims 74 and 75 have been added. Claims 1, 11, 12, 20, 21, 24-26, 74, and 75 are pending and under examination.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 3/18/2010 has been considered by the examiner. A signed copy is attached.

Response to Arguments/Amendments

Claim Objections

4. The rejections of claims 6, 13, 18, 19, and 73 are withdrawn in light of the cancellation of these claims. However, the subject matter of the cancelled claims that has been incorporated into other claims or new claims, may render the amended or new claims subject to the rejections of record.

Claim of Benefit and Rejections Maintained

Benefit

5. Applicant repeats arguments that have been raised multiple times, directed toward the claim of benefit. During the Interview held on 2 February 2010, the Examiner stated that she would once again review and consider Applicant's claim of benefit (see also Applicant's Remarks filed 3/18/2010, page 8). After additional consideration, Applicant's claim for benefit to provisional application 60/44,494, filed 31 January 2003, and provisional application 60/519,074, filed 10 November 2003, remains proper. However, benefit cannot be accorded to the provisional filings for the reasons set forth in detail of record. The denial of benefit, as stated in the Office Action of 11/29/2006 (page 4), is based on the fact that the scope of the provisional applications fails to correspond to the scope of the claims, as written. This is the nexus of the lack of enabling disclosure of the provisional applications to provide adequate support for the

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instantly claimed invention. See also the very detailed discussions in the Office Action mailed 8/9/2007, pages 2 and 3; the Office Action mailed 2/26/2008, pages 2-5, especially page 5; and the Office Action mailed 11/21/2008, pages 2-4. Benefit remains accorded to the instant filing date of 2 February 2004.

Provisional Obviousness-Type Double Patenting Rejection

6. The provisional rejection of claims 1, 11, 12, 20, and 23 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21-24 of copending Application No. 11/880,121, is maintained for the reasons of record. New claims 74 and 75 are also rejected for the same reasons of record.

Applicant states that the examiner has requested that a terminal disclaimer be filed. Applicant's statement is inaccurate. The examiner requires, pursuant to regulations, that a complete response be made to each rejection, including the instant provisional ODP rejection. Applicant is free to choose whether that response comprises argument and reasons why the rejection should not be maintained or whether to file a Terminal Disclaimer to obviate the rejection. Applicant has stated of record and has reiterated in the Remarks on page 14, that a Terminal Disclaimer will be filed over the claims of the '121 application when the instant claims are in condition for allowance. Accordingly, the rejection is maintained.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 11, 12, 20, 21, and 24-26, remain rejected and new claims 74 and 75 are rejected under 35 U.S.C. 102(a) and 35 USC 102(e) as being anticipated by Timans *et al.*, US Patent Application Publication 2002/0164609 A1 (publication date 7 November 2002) now US Patent 7,148,330 (12 December 2006, filed 30 November 2001), for the reasons of record and the reasons set forth herein.

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Applicant responds to all of the rejections under 35 USC 102(a), (b), and (e) (referring to the Timans et al., publication, the DeSavage et al., publication, the Bennett et al., publication, and the Matthews et al., patent in one responsive argument.

Applicant argues that the work done prior to Applicant's filing date indicated that one of skill in the art would have used IL-27 and IL-27R agonists to active the immune system (Remarks, p. 13). Applicant's response on pages 13 and 14 does not specifically address the cited Timans reference, but rather cites other references that have not been cited by the examiner in the rejection.

Applicant's arguments and the cited references are not persuasive. The instant rejection is not an obviousness rejection under 35 USC 103(a) where an analysis would include the state of the art at the time of the invention and the viewpoint of one of skill in the art. Instead, the rejection is an anticipation rejection.

As stated of record, IL-27R consists of a WSX-1/TCCR subunit and a gp130 subunit. Similarly, IL-27 consists of a p28 subunit and an EBI3 subunit. The IL-D80 taught by Timans et al., is also known as p28. The instantly claimed method requires administration of a IL-27R agonist to treat immune hyperactivity. As stated of record, Timans et al., teach the administration of IL-27 in the treatment of immune disorders and inflammation (paragraphs 14, 24, 36, 39, 42, 43, 161, and 204; see especially paragraph 39). Therapeutic administration in humans is taught at paragraphs 48 and 134. Diagnoses of subjects with an inflammatory condition as a prerequisite to administration is taught at paragraphs 128-133. Additionally, Applicant's attention is drawn to the fact that Timans teaches the use of IL-27 to treat inflammation (i.e. immune hyperactivity) at paragraph 39. Accordingly, the claims remain anticipated by Timans.

9. Claims 1, 11, 12, 20, 21, and 24-26, remain rejected and new claims 74 and 75 are rejected under 35 U.S.C. 102(b) as being anticipated by DeSavage et al., WO 01/29070 (26 April 2001) (see also US Patent Application Publication 2004/0234522 A1) for the reasons of record and for the reasons set forth below.

Applicant responds to all of the rejections under 35 USC 102(a), (b), and (e) (referring to the Timans et al., publication, the DeSavage et al., publication, the Bennett et al., publication, and the Matthews et al., patent in one responsive argument.

Applicant argues that the work done prior to Applicant's filing date indicated that one of skill in the art would have used IL-27 and IL-27R agonists to active the immune system (Remarks, p. 13). Applicant's response on pages 13 and 14 does not specifically address the cited DeSavage reference, but rather cites other references that have not been cited by the examiner in the rejection.

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Applicant's arguments and the cited references are not persuasive. The instant rejection is not an obviousness rejection under 35 USC 103(a) where an analysis would include the state of the art at the time of the invention and the viewpoint of one of skill in the art. Instead, the rejection is an anticipation rejection. As stated of record, DeSavage specifically teaches methods of treatment of diseases characterized by immune hyperactivation (see pages 59-63) using TCCR (WSX-1) polypeptides and antibodies, including agonist antibodies. Additionally, DeSavage also specifically contemplates inhibition of molecules with proinflammatory properties (i.e. to treat immune hyperactivity) at p. 63, line 36. Immune related diseases are defined on p. 8 of the specification as a disease in which a component of the immune system in a mammal caused, mediates, or otherwise contributes to morbidity in a mammal. Immune-mediated inflammatory diseases, non-immune mediated inflammatory diseases, infectious diseases, immunodeficiency diseases, and neoplasia are included in this definition (see, p. 8) and exemplified by disease name on p. 9. Methods of treatment using TCCR (WSX-1) polypeptides and antibodies to treat various immune related diseases and conditions such as T-cell mediated diseases, including those characterized by infiltration of inflammatory cells into a tissue, stimulation of T-cell proliferation, inhibition of T-cell proliferation, increased or decreased vascular permeability or the inhibition thereof, are taught, along with exemplary disorders and conditions on pp. 59-63 (compare new claims 74 and 75). See also, Example 12, pp. 79-81. The instant claims remain anticipated.

10. Claims 1, 11, 12, 20, 21, and 24-26, remain rejected and new claims 74 and 75 under 35 U.S.C. 102(b) as being anticipated by Bennett et al., WO 97/25425 (17 July 1997), for the reasons of record and for the reasons set forth herein.

Applicant responds to all of the rejections under 35 USC 102(a), (b), and (e) (referring to the Timans et al., publication, the DeSavage et al., publication, the Bennett et al., publication, and the Matthews et al., patent in one responsive argument.

Applicant argues that the work done prior to Applicant's filing date indicated that one of skill in the art would have used IL-27 and IL-27R agonists to active the immune system (Remarks, p. 13). Applicant's response on pages 13 and 14 does not specifically address the cited Bennett reference, but rather cites other references that have not been cited by the examiner in the rejection.

Applicant's arguments and the cited references are not persuasive. The instant rejection is not an obviousness rejection under 35 USC 103(a) where an analysis would include the state of the art at the time of the invention and the viewpoint of one of skill in the art. Instead, the rejection is an anticipation rejection. Bennett et al., teach methods of using the WSX-1 ligands (abstract), WSX-1 fusion proteins (p.

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4) and anti-WSX-1 receptor agonist antibodies (pp. 4-5) for the treatment of hematopoietic disorders such as leukemia, lymphoma, and infections (p. 6) (compare new claims 74 and 75). Additional therapeutic uses for the WSX-1 receptor are taught on p. 41. Therapeutic uses for WSX-1 receptor ligands and antibodies are taught on pp. 56-59. The instant claims remain anticipated.

11. Claims 1, 11, 12, 20, 21, and 24-26, remain rejected and new claims 74 and 75 under 35 U.S.C. 102(e) as being anticipated by Matthews *et al.*, US Patent 7,074,397 B1 (11 July 2006, benefit to 8 January 1996), for the reasons of record and the reasons set forth herein.

Applicant responds to all of the rejections under 35 USC 102(a), (b), and (e) (referring to the Timans *et al.*, publication, the DeSauvage *et al.*, publication, the Bennett *et al.*, publication, and the Matthews *et al.*, patent in one responsive argument.

Applicant argues that the work done prior to Applicant's filing date indicated that one of skill in the art would have used IL-27 and IL-27R agonists to active the immune system (Remarks, p. 13). Applicant's response on pages 13 and 14 does not specifically address the cited Matthews reference, but rather cites other references that have not been cited by the examiner in the rejection.

Applicant's arguments and the cited references are not persuasive. The instant rejection is not an obviousness rejection under 35 USC 103(a) where an analysis would include the state of the art at the time of the invention and the viewpoint of one of skill in the art. Instead, the rejection is an anticipation rejection.

As stated of record, Matthews *et al.*, teach methods of using agonist antibodies that bind to the WSX receptor (IL-27R) (column 3, lines 38-40, 46-47; column 14, lines 61-64, column 17, lines 14-16, column 44, line 22; column 80, lines 47-48 and 58-59; and column 45, beginning at line 36 to column 50) in the treatment of hematopoietic disorders, infections, and malignancies (column 50, lines 58-67 to column 51, lines 1-13) (compare new claims 74 and 75). Applicant's definition of the patient population includes individuals with the same disorders taught by the '397 patent as being treatable with agonist antibodies that bind the WSX receptor (IL-27R) (see especially, column 50, lines 58-67 to column 51, lines 1-13). The instant claims remain anticipated.

Conclusion

NO CLAIM IS ALLOWED.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERIE M. WOODWARD whose telephone number is (571)272-3329. The examiner can normally be reached on Monday - Friday 9:30am-6:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cherie M. Woodward/
Primary Examiner, Art Unit 1647